

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant:	Michael G. Orchard et al.	Examiner:	John Mabry
Serial No.:	10/560,383	Group Art Unit:	1625
Filed:	March 29, 2007	Docket No.:	AC-50-US
Title:	2-HYDROXYMETHYL-3,4,5- TRIHYDROXY-1-(4-PENTYLOXYBENZYL) PIPERIDINE AS GLYCOSYLCERAMIDE SYNTHASE (GCS) INHIBITORS	Confirmation No.:	9092

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**Response to Restriction Requirement**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir/Madam:

Pursuant to 37 C.F.R. §1.143, Applicants respond to the Restriction Requirement mailed December 30, 2009. The examiner issued a restriction as follows:

Group I, claims 1, 3 and 20, drawn to a compound and pharmaceutical composition comprising the compound 3,4,5-piperidinetriol, 2-(hydroxymethyl)-1-[(4-pentyloxy)phenyl]methyl]-, (2S, 3S, R4, 5S) and a compound of Formula III.

Group II, claim 4, drawn to a process of preparing a compound of claim 1.<sup>1</sup>

Group III, claims 21-35, drawn to method of inhibiting and treating a disease or condition as claimed comprising administering an effective amount of the compound of claim 1.

The Examiner argued that these claims do not relate to a single general inventive concept under PCT Rule 13.1 and 13.2. In particular, the Examiner alleged that the special technical feature is

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<sup>1</sup> Applicants respectfully note that the Examiner has mischaracterized claim 4. The Examiner noted that claim 4 is directed to a process of preparing compounds and pharmaceutical compositions of Formula III. However, claim 4 is directed to a process of preparing a compound as defined in claim 1, which process comprises reacting an intermediate compound of formula II with a 4-(pentyloxy)benzaldehyde along with other reagents or deprotecting an intermediate compound of formula III. Therefore, claim 4 is linked to the general inventive concept of the compound of claim 1.

found in EP 0536404 as described by Ezure et al. (Example No. 8 on page 10 and examples 12, 14, 15, 18 and 22) and therefore is not a contribution over the art.

Applicants respectfully disagree. Examples 8, 12, 14, 18, 18 and 22 of EP 0536402 cited by the Examiner all disclose the synthesis of deoxygalactostatin type compounds, which are (2R,3S,4R,5S)-2-Hydroxymethyl-3,4,5-piperidinetriol compounds, which compounds all have a different stereo configuration from the claimed invention (2S, 3S, 4R, 5S) and therefore is not anticipatory art. Because the compound as claimed in claim 1 is novel and that such compound links the inventions to a single general inventive concept, the restriction on the compound/pharmaceutical composition/intermediate compound claims and the method of use of such compound of claim 1 is improper. In addition, the MPEP provides that:

The method for determining unity of invention under PCT Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

(A) In addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product . . .

A process is specially adapted for the manufacture of a product if it inherently results in the product and an apparatus or means is specifically designed for carrying out a process if the contribution over the prior art of the apparatus or means corresponds to the contribution the process makes over the prior art.

MPEP 1850. As claim 4 is directed to a process of preparing the compound of claim 1 (please see footnote above), restrictions of claim 4 is also improper. Applicants earnestly request reconsideration of the restriction requirement.

In the event that the Examiner maintains the Restriction Requirement, and reserving all rights, including the right to reinstatement or rejoinder in the event the restriction requirement is withdrawn or a generic claim is allowed, and/or the right to pursue any non-elected inventions in divisional applications, Applicants provisionally restrict, with traverse, to Group I, claims 1, 3 and 20 and elect a compound as disclosed in Example 1, page 10 of the specification as a single species for search purposes. Applicants provisionally withdraw the remaining claims.

Reconsideration and withdrawal of the Restriction Requirement and a speedy allowance of the claims submitted is respectfully requested. The Examiner is invited to contact the undersigned by telephone in the event of any questions.

As this response is filed within one month from the date of the mailing of the restriction requirement, it is believed this response is timely and no fees are required. If this is not correct, however, please charge any additional fees, or credit any overpayment, to Deposit Account No. 50-4255

Respectfully submitted,

Dated: February 1, 2010

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